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May 15, 1995

**RESPONSE TO "NALED TASK 2B
REREGISTRATION DECISION: RESIDUE
CHEMISTRY CONSIDERATIONS"**

Case No.:	0092 Naled
EPA Chemical No.:	034401
EPA Company No.:	59639

RECEIVED

JUL 29 1998

OPP PUBLIC DOCKET

Mr. Lawrence J. Schnaubelt
Office of Pesticide Programs, H7504C
Document Processing Desk
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. Schnaubelt:

Valent appreciates the opportunity to review and respond to EPA's summary of residue chemistry considerations supporting the reregistration eligibility decision (RED) for naled. We are providing attached our detailed comments, and request that copies of these comments be distributed to all parties involved in the review of naled residue chemistry and/or dietary risk assessment. We also request that these comments be given serious consideration in the drafting of the final RED document.

Please contact Ms. Kelli Woodwick in our Washington D.C. office at (202) 872-4682, or myself at (510) 256-2770 if you have any questions regarding this submission.

Sincerely,

Daniel P. Fay

Daniel P. Fay
Project Manager
Registration & Regulatory Affairs

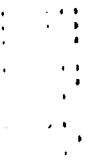
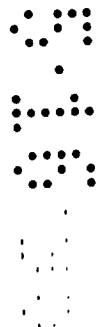
Attachment

DPF/

cc:

Ms. Brigid Lowery
Reregistration Review Manager
Special Review and Reregistration Division, EPA/OPP

Mr. Robert Forrest
Product Manager, PM Team 14
Registration Division, EPA/OPP



VALENT U.S.A. CORPORATION
Response to "Naled Task 2B Reregistration Eligibility Decision:
Residue Chemistry Considerations"

The following comments are provided to assist EPA/OPP regulatory officials in drafting a reregistration eligibility document for naled reflecting the most current and accurate information possible. Comments are generally provided in the order that the topics were addressed in the Agency's draft of residue chemistry consideration dated August 5, 1994. Page number references to Agency comments are provided in parentheses where appropriate.

GLN 171-3: Directions for Use (pp. 3-4)

1. The list of naled end use products registered to Valent is incorrect. The following listed products have been voluntarily cancelled:

<u>EPA Reg No.</u>	<u>Product Name</u>	<u>Date Cancellation Requested</u>
59639-14	DIBROM® 4 Dust	7/14/94
59639-25	DIBROM® LVC 10	7/14/94
59639-46	DIBROM® SEVIN® 4-5 Dust	9/13/94
59639-72	Naled 8 Insecticide	3/22/95
59639-74	Naled 85 Concentrate Insecticide	3/22/95

2. The following SLN with food/feed uses was not identified in footnotes to the table of registered products:

<u>EPA Reg. No.</u>	<u>Product Name</u>	<u>SLN No.</u>	<u>Use/Crop</u>
59639-15	DIBROM® 8 Emulsive	FL-890008	Lettuce

3. Footnotes to the table of registered products incorrectly list SLNs OR-900020 and WA-890019 as having food/feed uses. These SLNs are for alfalfa grown for seed only, and are designed specifically to prevent the possibility of human consumption of sprouted seed, or feeding of any treated plant part. This fact is acknowledged by the Agency for the Oregon SLN, under the Tolerance Reassessment Summary on page 49.

4. DIBROM Concentrate SLN Nos. FL-890003 and GA-770011 are listed as food/feed uses, presumably because rangeland or pasture are explicitly listed as use sites. SLN Nos. DE-910003 and DE-910004 modify the DIBROM Concentrate adult mosquito use directions without changing the sites of application on the Section 3 label, which include pastures, so these may also be considered potential feed uses.

5. A footnote to the table of registered products indicates that SLN No. MD-8100023 [sic] has expired. Valent disagrees. MD-810023 appeared on the latest EPA list of registrations for payment of maintenance fees, and Valent paid the fee for this registration in January 1995. Valent has received no expiration notice.
6. EPA is requesting Valent to specify maximum number of applications per growing season for each crop on the label, as supported by adequate residue data. If maximum single application rate, maximum seasonal use rate, minimum spray interval and pre-harvest interval are specified on the label, it is not necessary to specify maximum number of applications. In other words, if the label specifies a single application rate range (e.g. 1-2 pints per acre), the user should have the latitude to apply more applications at the low rate, as long as the labeled maximum seasonal rate, minimum spray interval and pre-harvest interval are not violated. Spraying more times at a lower rate should actually result in a lower dietary risk, due to the rapid dissipation of naled in the environment. Valent will submit label amendments accordingly, following issuance of the RED document.

GLN 171-4(a): Nature of the Residue in Plants (p. 4)

1. The acronym for bromodichloroacetaldehyde is BDCA, not BCDA.

GLN 171-4(c) and (d): Residue Analytical Method - Plants and Animals (p. 9)

1. Valent agrees to revise method RM-3G-4 to (1) eliminate testing of solvent and GC column for naled to DDVP conversion, and (2) revise the "CALCULATION" section to clearly state that the calculation of residue levels is intended to reflect the total residues of naled and DDVP, calculated as naled equivalents.

GLN 171-4(e): Storage Stability (pp. 9-10)

1. The Agency states that data are outstanding in support of tolerances for eggplant, winter squash, and alfalfa forage/hay. Valent disagrees. For eggplant, the Agency approved reinstatement of registration based on previously submitted data supporting tomatoes¹. No eggplant data have ever been submitted. The Agency has accepted storage stability data supporting tomatoes, therefore no eggplant storage stability data should be required. Valent does not intend to support reregistration of winter squash, and there is no tolerance required for alfalfa forage/hay, so no storage stability data should be required for these either.

¹D. McNeilly. 12/16/93. Memorandum to R. Cromwell/RD/PMT-14 regarding reinstatement of voluntarily cancelled naled uses.

GLN 171-4(k): Magnitude of the Residue in Plants (pp. 11-21)

1. **Sugar Beet Tops:** Valent submitted a request for voluntary cancellation of registration 59639-72 on 3/22/95 (see above under GLN 171-3, Section #1), therefore the requested action on p. 12 is no longer applicable.
2. **Lettuce:** Please see comments below under Tolerance Reassessment, Section #3.
3. **Cabbage, Cauliflower, Collards:** The Agency is requesting additional field trial data to obtain better geographic representation for these crops. Valent is interested in pursuing a crop group tolerance for Brassica leafy vegetables while addressing the Agency's request. A total of 17 trials are currently recommended to support establishment of a tolerance for this crop group². EPA has already reviewed data from a total of 14 trials on crops in this group, including broccoli (4), cabbage (2), cauliflower (2), collards (4) and kale (2). Note that the collards data includes two trials submitted in response to the 1991 Data Call-In in support of GLN 171-5.

Broccoli data is allowed as a substitute for cauliflower data in supporting the group tolerance. Since the geographical representation for broccoli residue trial data is considered by the Agency to be adequate, the requirement for additional cauliflower data in support of a crop group tolerance should be minimal. However, Valent agrees that existing data for cabbage and Brassica leafy greens (collards, kale) do not provide adequate geographic representation. Valent proposes the following program (EPA Region indicated in parentheses) to address the requirement for more geographically representative residue data, while simultaneously supporting a crop group tolerance for Brassica leafy vegetables:

Cabbage - three trials (I, II, VI)

Cauliflower - one trial (V)

Mustard Greens (in place of collards) - three trials (II, IV, VI)

4. **Kale:** The Agency is incorrect in stating that no field residue data exist for kale. Two trials have been conducted and submitted under EPA Acc. No. 73821, submitted 3/27/70. These data were reviewed in the 1983 residue chapter of the Naled Registration Standard.

²EPA/OPP/HED. 6/2/94. *EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances.*

5. **Bean Forage and Hay, and Pea Vines and Hay:** The American Crop Protection Association (ACPA) has submitted data and rationale supporting the removal of these commodities from the list of feed items requiring residue data.³ Based on these arguments, Valent requests that the Agency withdraw its request for additional data and tolerance proposals.
6. **Eggplant, Peppers:** The Agency is incorrect in stating that a maximum of three applications are allowed. Labeling approved by EPA allows 1-2 pints per application, otherwise specifying only maximum seasonal use rate, minimum spray interval, and pre-harvest interval. Thus, users may apply more than three applications at 1 pint each per acre, as long as other use restrictions are observed (see comment above under GLN 171-3, Section #6).
7. **Melons:** The Agency is incorrect in stating that use is restricted to a single application. Labeling approved by EPA allows 1-2 pints per application, specifying a maximum seasonal use rate of 2 pints, minimum spray interval, and pre-harvest interval. Thus, users may apply two applications at 1 pint each per acre, as long as other use restrictions are observed (see comment above under GLN 171-3, Section #6).
8. **Grapes:** Data submitted in support of GLN 171-4(l) should also be cited in support of GLN 171-4(k). These data support a three day PHI, which has been approved on amended DIBROM 8 Emulsive labeling.⁴
9. **Grass Hay:** The Agency incorrectly states that grass hay data are not available. Such data have been submitted and are in review under MRID 43536701.
10. **Hops:** The Agency does not acknowledge that data have been submitted by IR-4 in support of the hops tolerance. These data are in review under MRID 43493101.
11. **Tobacco:** The Agency fails to acknowledge that Valent requested cancellation of tobacco uses in its 90-day response to the 1991 Data Call-In, submitted January 23, 1992.

³Proposed Revisions to Table II - Animal Diet Preparation. Submitted to EPA by the American Crop Protection Association Table II Work Group in May 1995.

⁴R. Forrest. 12/15/94. Registration amendment approval letter to Valent.

GLN 171-4(1): Magnitude of the Residue in Processed Food/Feed (pp. 22-23)

1. **Oranges:** See discussion under Tolerance Reassessment, Section #9 below.
2. **Bean Cannery Waste:** Valent wishes to point out for the record that data were submitted in response to the Agency's 1991 Data Call-In requirement for a bean processing residue study (MRID 43065101). After these data were submitted, the Agency's requirement for such data was withdrawn.

GLN 165-1 and 165-2: Confined/Field Rotational Crop Accumulation (pp. 24-25)

1. Valent is not currently seeking any annual crop uses with rates higher than 2 lbs ai/acre, however, we do not agree with EFED's conclusion that a new confined rotational study should automatically be required if we choose to seek such a registration in future. Such a decision should be made in the context of *all* applicable data, including soil metabolism and crop residue decline. If warranted, other options, including crop rotation label restrictions greater than 30 days, should be considered as alternatives to costly additional radiolabel studies.

Tolerance Reassessment (pp. 49-53)

For all the tolerance actions required by EPA, it is Valent's understanding that tolerance fees will not be imposed.

1. **Tolerance Reductions:** Valent agrees with EPA's recommendations regarding reduction of tolerances *for the following crops only:* beans (dry and succulent), peas (succulent), sugar beet roots, cottonseed, and grapes. Please note the following comments for the remaining crops:
 - **Broccoli, Brussels sprouts:** EPA proposes revising broccoli and Brussels sprouts tolerances from 1 ppm to 0.1 ppm. Data submitted in 1966 (EPA Acc. No. 00073820) showed DDVP residues exceeded 0.2 ppm one day after the last of three applications at 2 lbs. ai/acre. Additional data, submitted in 1986 (EPA Acc. No. 00160765) showed maximum naled equivalent residues of 0.9 ppm one day following four applications at 1.8 lbs. ai/acre. Based on these data, we are concerned that there may be insufficient room in the revised tolerance to accommodate higher than average residues. Valent therefore proposes a slightly higher tolerance of 0.2 ppm for broccoli and Brussels sprouts to accommodate such residues.

- Celery: EPA proposes revising the celery tolerance from 3 ppm to 1 ppm. Data submitted in 1970 (EPA Acc. No. 00073821) showed maximum naled equivalent residues at 1 ppm one day after a single application at 1.5 lbs. ai/acre. Additional data submitted in 1986 (EPA Acc. No. 00160765) showed maximum naled equivalent residues of 0.88 ppm one day following five applications at 1.35 lbs. ai/acre. Based on these data, we are concerned that there may be insufficient room in the revised tolerance to accommodate higher than average residues. Valent therefore proposes a slightly higher tolerance of 1.5 ppm for celery to accommodate such residues.
- 2. Spinach and Swiss Chard Tolerances: A portion of the paragraph describing spinach data is missing from the draft of the document provided to Valent (p. 13). This section acknowledges that spinach data have been submitted, but states that a revised tolerance of 5 ppm will be necessary, neglecting the fact that the Agency reversed this position based on labeling of a 2 day pre-harvest interval (PHI).⁵ Both spinach and Swiss chard have been reinstated to the DIBROM 8 Emulsive label on this basis.
- 3. Tolerance Revocations: Valent confirms that tolerances for cucumbers, mushrooms, rice, tomatoes, and turnip tops are not being supported, therefore these tolerances may be revoked.

As for the lettuce tolerance, we have indicated in previous comments to the Agency⁶ that we would not support reregistration of lettuce. However, the loss of mevinphos, with its substantial use on lettuce, has prompted a reevaluation of our position. We have attached a letter from lettuce grower Mr. Raymond A. Ratto of Ratto Bros., Inc., Modesto, California, as evidence of the concern that lettuce growers have over the loss of mevinphos, and the interest in naled as a possible replacement. We are currently discussing this opportunity with Ratto Bros., Inc. in order to determine the best way to obtain a registration in California while protecting the interests of Valent and growers, as well EPA and the California Department of Pesticide Regulation. We recognize that residue data to support the lettuce tolerance are still outstanding, however, based on the unanticipated

⁵R. Forrest. 3/1/95. Letter to Valent regarding spinach/Swiss chard labeling and tolerances.

⁶D. Fay. 5/4/94. Letter to L. Rossi/SR&RD regarding final naled reregistration data call-in submission and reregistration status report.

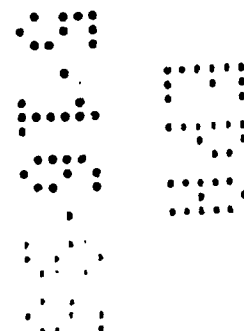
loss of mevinphos, we request that the Agency consider extending the naled lettuce tolerance on an interim basis pending further communication regarding a strategy for tolerance support.

4. **Forage Legumes Crop Group Tolerance:** Based on the ACPA document cited above under GLN 171-4(k) (Section #5), Valent proposes simple revocation of the forage legumes crop group tolerance, without replacement by individual tolerances for bean forage and hay and pea vines and hay.
5. **Citrus Crop Group Tolerance:** Valent does not object to establishment of a citrus crop group tolerance in replacement of individual tolerances for oranges, lemons, tangerines and grapefruit, provided the fee for establishment of such a tolerance is waived.
6. **Alfalfa Seed:** The Agency's statement regarding classification of alfalfa seed as a non-food use under the Oregon SLN (OR-900020) should be expanded to include equivalent uses under SLN's in Idaho (ID-900016), Utah (UT-940003) and Washington (WA-890019).
7. **Revision of Area Pest Control Tolerance Expression:** Valent agrees to revision of area pest control tolerance expression to include dichlorvos residues expressed as naled equivalents.
8. **New Tolerance Proposals:** Valent agrees to establishment of new tolerances for cotton gin byproducts, and grass hay (when submitted data have been evaluated), provided no fee is required.
9. **Food/Feed Additive Tolerance Issues:** The Agency cites data from an orange processing study, in which residues of dichlorvos concentrated 13x during processing. On p. 22, the following statement is also made: "Since dichlorvos, a metabolite of naled, is considered a carcinogen by the Agency, CBRS defers to OGC regarding the establishment of tolerances for commodities associated with processed fractions in which dichlorvos residues concentrate."

A recent statement made in the Federal Register (60 FR 24787, 5/10/95), in a notice of citrus tolerance establishment for diflufenzuron, appears to resolve the issue of the need for a naled/DDVP tolerance for citrus oil. EPA states: *EPA has determined that no section 409 tolerance is necessary for citrus oil because citrus oil is not a "ready to eat" processed food and "ready to eat" foods containing citrus oil are unlikely to have diflufenzuron residues greater than the citrus tolerance.* The notice goes on to state that significant dilution of citrus oil in "ready to eat" foods is the reason that residues in such foods would not exceed the citrus tolerance.

9

Valent submits that the diflubenzuron case applies to naled exactly. Based on a comparison of the proposed diflubenzuron citrus section 408 tolerances and 409 tolerance for citrus oil (0.5 ppm vs. 75 ppm), concentration of diflubenzuron residues in citrus oil is far greater than for naled residues. Thus, the rationale applied to withdraw the requirement for a section 409 tolerance for diflubenzuron in citrus oil also applies to naled.



RATTO BROS., INC.**GROWERS AND DISTRIBUTORS
FRESH VEGETABLES AND PRODUCE****6312 BECKWITH ROAD
MODESTO, CA 95358****AREA CODE 209
TELEPHONE 545-4445****May 11, 1995****Daniel P. Fay
Valent U.S.A. Corporation
No. California Blvd.
Walnut Creek, CA 94596****Dear Mr. Fay**

I am writing to express my concern regarding the loss of mevinphos for the late season insect pest control in lettuce. I urge Valent to use all available means to maintain the existing tolerance for naled in lettuce. Mevinphos has been a vital tool in lettuce production for many years for the pre-harvest cleanup of insect pests, especially for the very difficult to control aphid. As I have explained to Valent in the past, your Naled product, DIBROM 8 Emulsive, could fill the void left by the cancellation of mevinphos.

There are no other effective pre-harvest cleanup sprays registered on lettuce other than mevinphos at this time. Also, we have been given no guarantee by Bayer that their new active ingredient Imidacloprid will control aphids (our most difficult pest) all the way through harvest.

I understand that EPA is preparing to re-evaluate all naled tolerances, and that the lettuce tolerance could be revoked. Hopefully, if the tolerance can be maintained in effect for some additional time, it may be possible to reach an agreement for a DIBROM registration on lettuce that would be acceptable for all parties concerned (lettuce growers, EPA officials, and Valent).

Thank you for your understanding and consideration of our urgent need.

Sincerely,
Raymond A. Ratto Jr.
Raymond A. Ratto Jr.

